



ANSI-ASQ National Accreditation Board / ACLASS “DoD ELAP Lab Uncertainties”

2012 EMDQ Workshop • March 26 – 30, 2012 •

La Jolla, CA

ANSI-ASQ National Accreditation Board

Report Documentation Page				Form Approved OMB No. 0704-0188	
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1. REPORT DATE MAR 2012		2. REPORT TYPE		3. DATES COVERED 00-00-2012 to 00-00-2012	
4. TITLE AND SUBTITLE DOD ELAP Lab Uncertainties				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) ACLASS,500 Montgomery St. Suite 625,Alexandria,VA,22314				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES Presented at the 9th Annual DoD Environmental Monitoring and Data Quality (EDMQ) Workshop Held 26-29 March 2012 in La Jolla, CA. U.S. Government or Federal Rights License					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Same as Report (SAR)	18. NUMBER OF PAGES 22	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			



- Laboratories – ISO/IEC 17025
- Inspection Bodies – ISO/IEC 17020
- RMPs – ISO Guide 34 (Reference Materials)
- PT Providers – ISO 17043
- Product Certifiers – ISO Guide 65
- Government Programs: DoD ELAP, EPA Energy Star, CPSC Toy Safety, NRC, NIST IPV6, NLLAP, NEFAP
- TRAINING Programs



- Certification Bodies – *ISO/IEC 17021*
- Accreditation for Management System Certification Bodies that certify to :
 - *ISO 9001 (QMS),*
 - *ISO 14001 (EMS),*
 - *TS 16949 (US Automotive) etc.*



DoD ELAP Accreditation Overlaps ISO/IEC 17025

- DoD QSM 4.2 standard
- ISO/IEC 17025:2005
- Each has uncertainty sections
- Historical frameworks
 - DoD QSM – NELAC – MDLs, LODs, LOQs
 - ISO 17025 – GUM



Three Frameworks to Review

- ISO GUM
- MDL / LOD / LOQ
- Bill Ingersoll's "Nested Approach"



GUM Principles and Framework

- Major basis for ISO 17025 / ILAC uncertainties
- Basis for all calibration uncertainties reported
- Needs to be understood by both calibration and testing labs in ISO 7025
- Framework is:
 - Measurement value +/- uncertainty
 - typically 95% confidence
 - admittedly an estimate



GUM Uncertainty Calculations - 1

- Simple Excel table or more complicated if needed
- Outline calibration or test or process, often with flow chart
- Address and list all potential error sources
- Get values for all errors and get all in a common unit



GUM Uncertainty Calculations - 2

- Get all error factors into the standard uncertainty format
- Perform the root-sum-square combining function of the terms (GUM math)
- Expand the combined uncertainty to an expanded uncertainty by the coverage factor to give 95% confidence



GUM Uncertainty Application

- Framework should be same process for any calibration or test where uncertainty is warranted
- It is still an estimate
- ABs have testing uncertainty guidance to subgroup requirements, e.g., when UNC is not warranted



Uncertainty Requirements by Testing Categories (ACLASS)

1. Qualitative tests
2. Method-defined errors /
repeatabilities
3. Dimensional Inspection
4. Newly-created test
5. All others — miscellaneous



Recommended GUM Framework Item

- CONTROL CHARTS
- Repeatability / Reproducibility Studies



Nested Hierarchical Approach

“Environmental Analytical Measurement
Uncertainty Estimation”

Defense Technical Information Center
ADA 396946

William S. Ingersoll, 2001



Nested Approach to Uncertainty

- Follows the ISO GUM, but ...
- Addresses broader framework than most ISO 17025 scopes
- While ISO 17025 accounts for test uncertainty
- Nested approach covers more “project uncertainty” or environmental matrix uncertainty



Error Components in Nested Approach

- Analytical uncertainties
- Sampling uncertainties
- Sample planning uncertainties
- Matrix interferences
- Prep method effects
- Spike preparation effects



Nested Approach Uncertainties

- May be project-specified or mandated
- May be actually reported, while most DoD ELAP analyses uncertainties are not
- May represent combined errors beyond most ISO 17025 assessment scopes



3rd Framework – MDL / LOD / LOQ

ISO 17025- element 5.4.6.2

- Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement.
- Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.



3rd Framework – MDL / LOD / LOQ

- NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:
 - the requirements of the test method;
 - the requirements of the customer;
 - the existence of narrow limits on which decisions on conformity to a specification are based.



3rd Framework – MDL / LOD / LOQ

- This framework may sometimes REPLACE full ISO GUM uncertainty determinations.
- Mathematical principles are internationally understood and accepted
- Includes repeatability, accuracy (bias) and precision studies
- Needs GUM practice in addition if other errors not accounted for



How to avoid confusion ?

- Uncertainty is unfortunate term
- We want to replace it when possible with the term “confidence level” (95%)
- ISO 17025 framework and the ISO GUM practices are the typical scenarios
- In most reports, labs are not reporting uncertainties and have not directly calculated them
- Control charts and regular LOD/LOQ updating



Location of ACLASS and ANAB Offices

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- ANAB → 600 N. Plankinton Ave.
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Milwaukee, WI 53203



ACCLASS Parents / Owners

- **ANSI** – American National Standards Institute
(offices in “L” St. in Washington, D.C.
and W. 43rd St. in New York City)
- **ASQ** – American Society for Quality
(same address as ANAB) – ASQ building



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Questions

